REMARKS

Claims 43-47 are pending and under examination in the subject application. By this Amendment, applicant has amended claims 45-47 and added claims 69 and 70 to make certain formatting changes. Accordingly, claims 43-47, 69 and 70 will be pending and under examination in the subject application upon entry of this Amendment.

In view of the remarks below, applicant maintains that the Examiner's rejections have been overcome, and respectfully requests that they be withdrawn.

Formalities

Priority

The Examiner objected to the claim of priority of the subject application to provisional application no. 60/168,151. The Examiner alleges that the MUM-3 gene is only mentioned by name and no description of the gene is provided in the provisional application. The Examiner further alleged that neither MUM-2 nor MUM-3 is related to the claimed invention.

In response, applicant respectfully disagrees with the Examiner's position. Applicant directs the Examiner's attention to Figure 2 which details both a restriction map and a genomic linkage map of the MUM-3 gene. Further Figure 4 depicts the structure and expression pattern of MUM-3 mRNA. Figures 6a-c disclose the nucleic acid sequences and amino acid sequences of all three isoforms of MUM-3, which correlate

with the three isoforms of IRTA-2, namely IRTA-2a, IRTA-2b and IRTA-2c. The sequences for the IRTA-2 gene and its protein isoforms are disclosed in Figure 18B1-B3 of the instant application which parallel Figures 6a-c of the provisional application.

In view of these remarks, applicant maintains that the claim of priority to provisional application no. 60/168,151 is proper. Accordingly, applicant maintains that the priority date to which the claimed subject matter is entitled is November 28, 1999.

Specification

The Examiner objected to the specification as allegedly containing an embedded hyperlink and/or other form of browser-executable code. In response, but without conceding the correctness of the Examiner's objection, applicant notes that the specification has been amended to delete the internet address, thereby obviating the Examiner's objection.

Oath/Declaration

The Examiner objected to the oath or declaration as allegedly defective because it recites priority to the provisional application of 60/168,151. In response, applicant maintains that, in light of the arguments above, the objection to the priority claim has been overcome, thereby obviating the Examiner's objection to the oath or declaration.

Claim Objection

The Examiner objected to claim 45 under 37 C.F.R. §1.75(c) as allegedly being of improper dependent form for failing to further limit the subject matter of a previous claim. In response, and without conceding the correctness of the Examiner's objection, applicant notes that claim 45 has been amended to recite one embodiment of the antibody claimed, and new claim 69 has been added to recite the other, thereby obviating the Examiner's objection.

Rejection Under 35 U.S.C. §112, Second Paragraph

The Examiner rejected claims 43-47 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner alleges that claims 43-47 are rendered vague and indefinite by the recitation of IRTA2 as the only means of identifying the protein to which the antibodies bind.

In response, applicant respectfully traverses the Examiner's rejection. Applicant contends that the language in claims 43-47 and new claims 69 and 70 particularly points out and distinctly claims the subject invention. According to M.P.E.P. §2173.01, "[a] fundamental principle contained in 35 U.S.C. 112, second paragraph, is that applicants are their own lexicographers." Furthermore, a claim may not be rejected solely because of the type of language used to define the subject matter claimed. *In re Swinehart*, 439 F2d 210, 160

USPQ 226 (CCPA 1971). Applicant maintains that IRTA, Immunoglobulin superfamily Receptor Translocation Associated, proteins are well defined in the subject specification.

The IRTA2 protein is a transmembrane protein belonging to a new subfamily of the immunoreceptor superfamily. The IRTA2 isoforms share in common a signal peptide and six extracellular Ig-type domains, as shown in Figure 9B. IRTA2a comprises a 759-amino acid protein with eight Ig-type domains and a unique 13-amino acid sequence at its C-terminus. IRTA2b comprises a 592-amino acid protein with six Ig-type domains. IRTA2c comprises a 977-amino acid protein with nine Ig-type domains, a 23-amino acid transmembrane domain and a 104-amino acid cytoplasmic domain with three SH2-binding motifs. Accordingly, applicant maintains that the IRTA2 protein to which the claimed antibody binds is defined in the specification and directs the Examiner's attention to the relevant parts of the specification *inter alia* at page 39, line 31 to page 40, line 2; *inter alia* at page 66, line 21 to page 67, line 21; *inter alia* at page 67, line 26 to page 68, line 20; *inter alia* at page 71, line 25 to page 72, line 6; *inter alia* at page 74, line 26 to page 75, line 27 and *inter alia* at Figures 18B-1 to 18B-3.

Hence, applicant maintains that the recitation of IRTA2 in claim 43 has a well-defined meaning which can be found in the specification. Accordingly, applicant maintains that the rejected claims contain well defined terms and particularly point out the subject matter which applicant regards as the invention.

The Examiner further alleges that the recitation of "monoclonal" in claim 46 lacks antecedent basis in claim 43 and that the recitation "toxoid" in claim 47 renders the claim vague and indefinite as the specification does not provide a definition for a toxoid that would differentiate it from a toxin.

In response, but without conceding the correctness of the Examiner's rejection, applicant notes that claims 46 and 47 have been amended, thereby obviating the Examiner's rejection.

In view of these remarks, applicant maintains that claims 43-47 satisfy the requirements of 35 U.S.C. §112, second paragraph, and respectfully requests that the rejection be withdrawn.

Rejection Under 35 U.S.C. §112, First Paragraph

The Examiner rejected claims 43-47 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner alleges that the genus of proteins is highly varied as structural attributes which define the proteins of the genus are missing from the claims.

In response, applicant respectfully traverses the Examiner's rejection.

The test for written description under 35 U.S.C. §112, first paragraph, is whether the disclosure describes the claimed invention in sufficient detail so that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. According to M.P.E.P. §2163(I)(A), when evaluating whether support in the specification for the original claims is sufficient, "[t]here is a strong presumption that an adequate written description of the claimed invention is present when the application is filed." *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976). The initial burden is therefore on the Examiner to present evidence of the lack of written description. Applicant maintains that the claimed invention satisfies the test for adequate written description, and that the Examiner has not set forth sufficient grounds for concluding otherwise.

Applicant respectfully disagrees with the Examiner's position. The subject invention provides antibodies directed to an IRTA2 protein. As the Examiner concedes the specification provides a description of three isoforms of IRTA2. These isoforms are identified in the instant specification, *inter alia*, at page 66, line 21 to page 67, line 21, shown in Figures 18B1-B3 and SEQ ID NOs. 44, 3 and 41.

Moreover, according to M.P.E.P. §2163 (II)(A)(3)(a)(ii), the written description for a claimed genus may be satisfied by disclosure of relevant, identifying characteristics sufficient to show the applicant was in possession of the claimed genus. *Regents of the University of California v Eli Lilly*, 119 F3d. 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998). Satisfactory disclosure depends

on whether the necessary common attributes of the genus are recognized by one skilled in the art in view of the species disclosed. Applicant maintains that the claimed genus is supported by the disclosed species, and that the species disclose the necessary attributes of the claimed genus.

The claimed genus comprises IRTA2 proteins which share in common a 560-amino acid sequence comprising a signal peptide and six extracellular Ig-type domains, as shown in Figure 9B. The disclosed species include the three isoforms IRTA2a, IRTA2b and IRTA2c. One skilled in the pertinent art would recognize this homology as a common attribute by which the genus is defined. Accordingly, applicant maintains that one skilled in the art would easily recognize the commonality of the claimed genus in view of the disclosed species.

In view of these remarks, applicant maintains that claims 43-49 are adequately supported by the disclosure and satisfy the requirements of 35 U.S.C. §112, first paragraph.

Rejection Under 35 U.S.C. §102(b)

The Examiner rejected claims 43-45 under 35 U.S.C. §102(b) as allegedly anticipated by the abstract of Medesan et al. Specifically, the Examiner alleges that Medesan et al. disclose heat aggregated human serum IgG, thus fulfilling the specific embodiments of the claims.

In response, applicant respectfully traverses the Examiner's rejection.

Medesan et al. teach that heat aggregated human serum IgG binds with Fc receptors present on mouse peritoneal macrophage.

In support of this rejection, the Examiner points to the specification which discloses, at page 80, lines 13-14, that IRTA2c binds to heat aggregated human serum IgG.

Applicant respectfully disagrees with the Examiner's interpretation of the teachings of Medesan et al. as they apply to the claimed invention. Under 35 U.S.C §102(b), a person shall be entitled to a patent unless "the invention was patented or described in a printed publication in this or a foreign country", more than one year prior to the date of filing the application for patent. According to M.P.E.P. §2131, "[t]o anticipate a claim, the reference must teach every element of the claim."

Claim 43-45 provide for antibodies directed to an IRTA2 protein. As stated above, IRTA2 has a well defined meaning in the instant specification. Medesan et al. do not teach the human IRTA2 protein expressed in human B-cells, but instead suggests that two types of Fc receptors may be present on mouse peritoneal macrophages. Therefore, Medesan et al. do not teach each and every element of the rejected claims

The Examiner further rejected claims 43-45 under 35 U.S.C. §102(b) as allegedly anticipated by Zipf et al. as evidenced by the abstract of Callahan et al. and Macardle et al. Specifically, the Examiner alleges that Zipf et al. disclose a monoclonal antibody of 41H.16 and Macardle teaches that the

41H.16 antibody is an anti-CD32 that binds to FcgammRIIb. Callahan et al. teaches overexpression of FcgammRIIb2 in a follicular lymphoma cell line exhibiting a 1q21 translocation.

In response, applicant respectfully traverses the Examiner's rejection.

In support of the rejection, the Examiner alleges that the instant specification teaches that IRTA2 mRNA expression is high in centrocytes and germinal center B-cells and that the expression of IRTA2 protein is deregulated due to a 1q21 translocation. The Examiner further concludes that one skilled in the art would allegedly conclude that IRTA2 has the same characteristics as FcgammRIIb2.

Applicant respectfully disagrees with the Examiner's interpretation of the cited references as they apply to the rejected claims. Applicant again notes that IRTA2 is well defined in the specification as detailed above. Zipf et al do not teach the IRTA2 protein. Furthermore, one skilled in the pertinent art would recognize that the disclosed IRTA2 amino acid sequences differ from that of FcgammRIIb2. One skilled in the art would also recognize that the location of the translocation on gene 1 disclosed in Callahan et al., namely (q12;q11), does not correspond to the translocation location disclosed in the specification, (q21;q32).

Applicant maintains that neither Zipf et al. as evidenced by Callahan et al. and Macardle et al. nor Medesan et al. disclosed the elements of the rejected claims, namely they do not disclose the novel IRTA2 protein. Accordingly, applicant

maintains that claims 43-45 are not anticipated by the cited references.

In view of these remarks, applicant maintains that claims 43-45 satisfy the requirements of 35 U.S.C. §102(b).

Rejection Under 35 U.S.C. §103(a)

The Examiner rejected claims 43-47 under 35 U.S.C. §103(a) as allegedly unpatentable over Schlom in view of Zipf et al., the abstract of Callahan et al., Macardle et al. and Latour et al.

In response to the Examiner's rejection, applicant respectfully traverses, and maintains that the Examiner has failed to establish a *prima facie* case of obviousness.

To establish a *prima facie* case of obviousness, the Examiner must demonstrate three criteria with respect to each claim. First, the cited references, when combined, teach or suggest every element of the claim. Second, one of ordinary skill would have been motivated to combine the teachings of the cited reference at the time of the invention. And third, there would have been a reasonable expectation that the claimed invention would succeed.

In light of these requirements, applicant maintains that the cited references fail to support a *prima facie* case of obviousness for claims 43-47.

As stated above, claims 43-45 provide for antibodies directed to an IRTA2 protein. This invention is based on applicant's

discovery of the novel IRTA genus of proteins, to which IRTA2 belongs. The cited references, in combination, fail to teach all elements of the independent claim 43. In particular, these references fail to teach the IRTA2 protein.

According to the Examiner, Schlom teaches anti-tumor antibodies conjugated to drugs; Latour et al. teach that antibodies which bind to FcgammaRIIb2 are internalized; and the combination of Zipf et, the abstract of Callahan et al. and Macardle et al. teach that the anti-CD32 antibody binds to the FcgammaRIIb2 receptor which is overexpressed in a cell line derived from a lymphoma patient. Again, none of these references teaches the IRTA2 protein of the instant claims which applicant first isolated. Moreover, the specification teaches the differences between the IRTA and Fc receptors. As detailed *inter alia* at page 68, lines 1-20, the IRTA and Fc receptors belong to the same superfamily of receptors. They share homology in their extracellular domain (37% identity and 50% similarity), but no homology exists between IRTA and Fc receptor cytoplasmic domains. The lack of homology in the cytoplasmic domain suggests that the employment of different signaling pathways by these different proteins, and demonstrates that IRTAs and FC receptors are not the same proteins.

For the reasons above, the cited references combined fail to teach the elements of the claimed assay. Absent such teaching, there could not have been a motive to combine or a reasonable expectation of success.

In view of the above remarks, applicant maintains that the

Examiner has failed to set forth a *prima facie* case of obviousness, and that accordingly, claims 43-47 and new claims 69 and 70 satisfy the requirements of 35 U.S.C. §103(a).

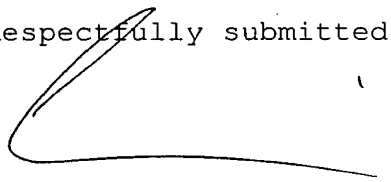
Summary

For the reasons set forth hereinabove, applicant respectfully requests that the Examiner reconsider and withdraw the rejections, and solicits allowance of the pending claims.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicant's undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. However if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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10/31/03

Alan J. Morrison Date
Reg. No. 37,399

John P. White
Registration No. 28,678
Alan J. Morrison
Registration No. 37,399
Attorneys for Applicant
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036
(212) 278-0400